UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,263	10/31/2000	Anthony J. Cutie	540541-2013.1	1107

20999 7590 01/03/2002

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/702,263	CUTIE ET AL.	
	Examiner	Art Unit	
	Robert M DeWitty	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-17 are pending in the instant application. Acknowledgement is made of Applicant's change of address submitted 4/30/01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-6, 9-17 are rejected under 35 U.S.C. 103(a) as obvious over Whitcomb (U.S. Pat. No. 6,011,049).

Whitcomb relates to combinations of a glitazone agent and a biguanide for the treatment of diabetes mellitus and improvement of glycemic control. In use, it is taught that compounds can not only be employed individually, but also combined in a single formulation, such as a tablet, or capsule (col. 4, lines 31-37). Dosage amounts can be from 5mg to 2500mg for the glitazone. A preferred combination is pioglitazone plus metformin. These combinations produce better than expected control of non-insulin dependent diabetes mellitus (NIDDM) (col. 5, lines 2-6). The compositions may contain common excipients, including starch, sucrose, talc, gellatin, methylcellulose, and magnesium stearate (col. 5, lines 27-29).

The combined pioglitazone plus metformin may take the form of a tablet. One with ordinary skill in the art would know that in the formation of the tablet, the

ingredients would be compressed together, thereby allowing a portion of metformin to be covered with pioglitazone, i.e., forming a core and a first layer.

Whereas Whitcomb does not teach a first layer comprised of pioglitazone hydrochloride, or a core comprised of biguanide whereby a portion is covered by the first layer, there is no evidence of criticality in comparison to Whitcomb invention wherein a glitazone agent and a biguanide are used in combination in a tablet. Further still, Applicant's instant specification points out that depending on the rate of administration "...either the first layer or the core may contain a mixture of the two active ingredients or both the first layer and the core may contain the two active ingredients..." (page 3, second full paragraph).

2. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieveley (U.S. Pat. No. 6,153,632).

Rieveley teaches the treatment of diabetes mellitus by incorporating a therapeutic amount of one or more insulin sensitizers along with one or more orally ingested insulin (Abstract). It is taught that a major problem with the application of orally ingested insulin is that acids and enzymes destroy most of it, thereby reducing the amount available to the bloodstream (col. 2, lines 64-67). By combining an insulin sensitizer with the insulin, the insulin sensitizer enables lower levels of insulin that reach the bloodstream to be sufficient for purposes of enabling the cells of the body to function with lower levels of the insulin (col. 5, lines 52-67). A list of suitable insulin sensitizers includes pioglitazone HCl (col. 2, lines 34-35). The insulin that can be used in the oral

dosage form includes a biguanide (examples being Metformin and Glucophage (col. 3, lines 23-25).

Rieveley further teaches that time release systems can be used to incorporate the insulin with appropriate time release mechanisms so the insulin is not released until after the time release-insulin combination has passed through the stomach and the preliminary stages of the digestive process (col. 3, lines 1-9).

As above, Rieveley does not explicity state the use of pioglitazone HCl in the first layer and a biguanide at the core, a portion covered by the first layer, but because there is no evidence of criticality in such Applicant's formulation, the instant invention is made obvious by Rieveley.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

SABIHA QAZI, PH.D
PRIMARY EXAMINER